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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/050,441 | 01/16/2002 | Bert Steffen Rosen | INL-44C1 | 7644 |

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| EXAMINER | |
|-------------------------|--------------|
| GITOMER, RALPH J | |
| ART UNIT | PAPER NUMBER |
| 1651 | 3 |
| DATE MAILED: 12/23/2002 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

[Handwritten signature]

Office Action Summary

Application No.
10/050,441

Applicant(s)

Rosen et al.

Examiner

Ralph Gitomer

Art Unit
1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 16, 2002

2a) This action is FINAL.

2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 45-84 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 45-64 and 66-84 is/are rejected.
- 7) Claim(s) 65 is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

6) Other: _____

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The preliminary amendment received 1/16/02 has been entered
and claims 45-84 are currently pending in this application.

5 The nonstatutory double patenting rejection is based on a
judicially created doctrine grounded in public policy (a policy
reflected in the statute) so as to prevent the unjustified or
improper timewise extension of the "right to exclude" granted by
a patent and to prevent possible harassment by multiple
assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.
10 Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.
1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);
In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re
Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15 A timely filed terminal disclaimer in compliance with 37 CFR
1.321(c) may be used to overcome an actual or provisional
rejection based on a nonstatutory double patenting ground
provided the conflicting application or patent is shown to be
commonly owned with this application. See 37 CFR 1.130(b).

20 Effective January 1, 1994, a registered attorney or agent of
record may sign a terminal disclaimer. A terminal disclaimer
signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 45-64, 66-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,395,501. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '501 include an exogenous substrate and the present claims do not specify such a substrate. However, the present claims written in open-ended ~~comprising~~ terminology do not exclude such a substrate.

Claims 45-64, 66-84 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 45 lacks a correlating step at the end to accomplish the preamble. Claim 46 and all occurrences fails to further limit claim 45 from which it depends because claim 45 does not contain Mg+2 ion in step (d). Claim 63 may contain a typographical error. Claim 70 contains improper Markush terminology.

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Claim 65 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternative. See MPEP § 608.01(n). Accordingly, the claim 65 has not been further treated on the merits.

5 The following prior art pertinent to applicant's disclosure
is made of record and not relied upon:
Voorberg (6,083,905) teaches diagnostic tests related to
activated protein C.
Rosen (6,395,501) is the parent patent.
10 Stocker (6,426,192) teaches disorders in the protein C system.

15 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to

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patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button **Patent Electronic Business Center** for more information.

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Ralph Gitomer
Ralph Gitomer
Primary Examiner
Group 1651

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HALPH GITOMER
PRIMARY EXAMINER
GROUP 1200